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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,383	05/26/2005	Martin Rahe	UC 207-KFM	4932

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MILDE & HOFFBERG, LLP
10 BANK STREET
SUITE 460
WHITE PLAINS, NY 10606

EXAMINER	
HELM, CARALYNNE E	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
10/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,383	RAHE ET AL.	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2008 and 21 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,8,9,11,18,20 and 21* is/are pending in the application.

4a) Of the above claim(s) *3,11 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 8-9, and 20-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/27/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Note to Applicant: References to paragraphs in non-patent literature refers to full paragraphs (e.g. 'page 1 column 1 paragraph 1' refers to the first full paragraph on page 1 in column 1 of the reference).

Information Disclosure Statement

The information disclosure statement filed September 6, 2005 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered.

Election/Restrictions

Applicant's election with traverse of a device with a germicide and a shape memory carrier that dissolves in the restriction requirement in the reply filed on March 27, 2008 and August 21, 2008 is acknowledged. The traversal is on the grounds that limitations amended into the claim are not met by the prior art cited that demonstrated a lack of unity in the invention. This is not found persuasive because the prior art did teach the common technical feature of a device that comprises a germicide that connected the inventions of the pending claims at the time of the action. Applicant's arguments relative to the newly added limitations in the claims are moot in view of the lack of unity demonstrated for the inventions originally presented and the rejections under §103 set forth below.

The requirement is still deemed proper and is therefore made FINAL.

Claims 3, 11, and 18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 112

> The following is a quotation of the first paragraph of 35 U.S.C. 112:
> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating a urinary bladder infection with a device having silver or known pharmaceutical antibiotics as an active agent with germicidal properties, does not reasonably provide enablement for preventing urinary bladder infections with the same device, treatment or prevention of urinary bladder infection with magnesium oxide or any other unnamed active agent with germicidal properties. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Although the recitation of the intended use of preventing and treating is not given patentable weight in terms of prior art, it is considered regarding its fulfillment of the enablement requirements of 35 U.S.C. 112, first paragraph.

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence or absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art,

7) the predictability of the art, and

8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. In re Fisher, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970).

The disclosure only specifies two options for compounds that are envisioned as being active agents with germicidal properties, silver and magnesium oxide. Although silver is well known for its antibacterial properties, its abilities to *prevent* infection when incorporated in implanted devices have not been demonstrated by the applicant, or others. Since the instant specification provides no limiting definition of the term "preventing", the examiner will adopt the broadest reasonable interpretation for same. The Penguin English Dictionary defines "prevent" as "to stop from happening or existing", i.e., to completely eradicate. The claims are thus very broad insofar as they recite "preventing" urinary bladder infection,, i.e., the complete eradication of same. While such "prevention" might theoretically be possible under strictly controlled laboratory conditions, as a practical matter it is nearly impossible to achieve in the "real world" in which patients live; urinary bladder infections are always a risk. Darouiche (Clinical Infection Diseases 1999 29:1371-1377) discusses the efficacy of silver containing implants at reducing bacterial growth and subsequent infection but infection still occurs (see page 1371 column 2 paragraph 2-page 1372 column 2 line 2). This indicates that even in the case of effective treatment, infection was not prevented. Thus prevention of infection by a device having silver as an active agent with germicidal properties is by no means predictable.

Applicant provides no data, references, or discussion to demonstrate prevention or even treatment of urinary bladder infection with magnesium oxide. Sawai et al. (World Journal of Microbiology & Biotechnology 2000 16:187-194) detail in vitro studies

where magnesium oxide powder was shown to act as an antibacterial compound (see page 189 column 2 paragraph 1). However, its efficacy at treating infection in an in vivo setting has yet to be shown. As discussed above in reference to the ability of silver to prevent urinary bladder infection, the same issues arise in regards to magnesium oxide preventing urinary bladder infection. Therefore in both the case to treatment and prevent of urinary bladder infections with magnesium oxide, the degree of predictability is low.

Applicant claims no particular compounds as active agents with germicidal properties so the particular compounds claimed within this genus are unreasonably numerous. Since the all the compounds that fall within this genus were not known at the time of the invention, their function as a treatment or preventative within a device for urinary bladder infections is highly unpredictable.

Because of the known unpredictability of the art, and in the absence of experimental evidence, no one skilled in the art would accept the assertion that the instantly claimed agents could be predictably used to prevent or treat urinary bladder infections as inferred by the claim and contemplated by the specification. Accordingly, the instant claims do not comply with the enablement requirement of §112, since to practice the invention claimed in the patent a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite properties of the claimed device that are not defined including “adapted to be inserted” in claim 1 and “shape suitable for the purpose” 21. These recitations do not clearly set forth and particular shape or size

such that one of ordinary skill in the art would be able to ascertain the true metes and bounds of the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of Graham v. John Deere Co. have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 8-9, and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lendlein et al. (US PGPub No. 2006/140999) in view of Modak et al. (US PGPub No. 2001/0010016).

Lendlein et al. teach a polymeric implantable medical device (carrier) with a drug (see paragraph 42, claims 1 and 5; instant claim 1). Lendlein et al. go on to teach that the drug is preferably an antibiotic an exemplifying gentamicine as one particular variety known for use in such devices (see paragraph 62; instant claims 1 and 20). Further the device is taught to contain polymer that is biodegradable (adapted to dissolve or disintegrate) and has shape memory properties (see paragraphs 42-44; instant claims 1, 8, and 21). The degradation properties recited in instant claim 9 are necessarily present in any carrier composed of a biodegradable polymer, where the carrier properties and structure determine the kinetics of its degradation. A recitation of the intended use (in the instant case “for preventing and treating urinary bladder infections”) of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The device taught by Lendlein et al. would be capable of the recited intended use when employing drugs known for treating bacterial infections. In addition, the device is taught to be shaped as particles, threads (elongated shape) or films; thus the implant is also capable of being “pushed into the bladder space directly or with the use of a catheter or another suitable device through the urethra" and “adapted to be inserted and forming an implant body in the urinary bladder” (see claim 19). Since the polymer (active agent carrier) that makes up the implant is a biodegradable material, after a sufficiently long enough time such that device has eroded to a size dimension similar to that of the urethra, the device would be able to be "…flushed out through the urethra together with the active agent”. In view of the teachings of Lendlein et al. it

would have been obvious to one of ordinary skill in the art at the time the invention was made to make a device composed of a biodegradable, shape memory polymer as well as an active agent with germicidal properties wherein the device has all of the claimed properties. Lendlein et al. does not teach a particular compound with germicidal properties.

Modak et al. teach a set of implantable polymeric medical devices that contain antimicrobial compounds (see abstract and paragraph 14 and 48; instant claim 1). Modak et al. go on to particularly teach silver as a preferred compound for such a device (see paragraph 16; instant claim 1). Since Modak et al. and Lendlein et al. both teach polymeric, implantable medical devices with germicidal compounds, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the particular compounds taught by Modak et al. in the device of Shaddock. Thus claims 1, 8-9, and 20-21 are obvious over Lendlein et al. in view of Modak et al.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615